General

Guideline Title

New generation cardiac CT scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash) for cardiac imaging in people with suspected or known coronary artery disease in whom imaging is difficult with earlier generation CT scanners.

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). New generation cardiac CT scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash) for cardiac imaging in people with suspected or known coronary artery disease in whom imaging is difficult with earlier generation CT scanners. London (UK): National Institute for Health and Care Excellence (NICE); 2012 Jan. 32 p. (Diagnostics guidance; no. 3).

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

New generation cardiac computed tomography (CT) scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD, and Somatom Definition Flash) are recommended as an option for first-line imaging of the coronary arteries in people with suspected stable coronary artery disease (with an estimated likelihood of coronary artery disease of 10% to 29%, as described in the National Institute for Health and Care Excellence [NICE] guideline Chest pain of recent onset: assessment and diagnosis of recent onset chest pain or discomfort of suspected cardiac origin [NICE clinical guideline 95]) in whom imaging with earlier generation CT scanners is difficult.

New generation cardiac CT scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD, and Somatom Definition Flash) are recommended as an option for first-line evaluation of disease progression, to establish the need for revascularisation, in people with known coronary artery disease in whom imaging with earlier generation CT scanners is difficult. CT scanning might not be necessary in situations in which immediate revascularisation is being considered.

Service providers, working with commissioners and cardiac networks, should take into account the benefits of access to new generation cardiac CT scanners for use in the circumstances described above. They should do this when selecting CT scanners as part of medium term asset planning.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Coronary artery disease

Guideline Category

Diagnosis

Evaluation

Technology Assessment

Clinical Specialty

Cardiology

Family Practice

Internal Medicine

Radiology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Physician Assistants

Physicians

Guideline Objective(s)

To assess the diagnostic accuracy, effect on patient outcomes and cost effectiveness of specific new generation cardiac computed tomography (CT) scanners

Target Population

- Adults (18 years or older) with suspected coronary artery disease in whom imaging with earlier generation computed tomography (CT) is difficult and with a 10% to 29% pre-test likelihood of coronary artery disease
- Adults (18 years or older) with known coronary artery disease in whom imaging with earlier generation CT is difficult and in whom revascularisation is being considered

Interventions and Practices Considered

New generation cardiac computed tomography (CT) scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash) for cardiac imaging

Major Outcomes Considered

- Impact of testing on treatment plan (e.g., surgical or medical management), where information on the appropriateness of the final treatment plan was also reported
- Impact of testing on clinical outcome (e.g., angina, myocardial infarction, cardiovascular mortality)
- Test accuracy
- Indeterminacy (test failure rate)
- Acceptability of tests to patients
- Adverse events associated with testing
- Radiation dose associated with imaging
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an External Assessment Group to perform a systematic literature review on the technology considered in this diagnostics guidance and prepare a Diagnostics Assessment Report (DAR). The DAR for this guidance was prepared by Kleijnen Systematic Reviews Ltd. (see the "Availability of Companion Documents" field).

Assessment of Clinical Effectiveness

Inclusion and Exclusion Criteria

Participants

Study populations eligible for inclusion were:

- Adults (≥18 years) with known (previously diagnosed who have symptoms that are no longer controlled by drug treatment and/or who are being considered for revascularisation) or suspected (chest pain or other suggestive symptoms) coronary artery disease (CAD), who are difficult to image (not currently candidates for CT imaging). Difficult or impossible to image patient groups defined *a priori* were:
  - Obesity (body mass index [BMI]≥30 kg/m^2)
  - High levels of coronary calcium (calcium score >400)
  - Arrhythmias (including, but not limited to atrial fibrillation [AF])
  - High heart rate (HHR) (>65 bpm)
  - Intolerance of beta-blockers
  - Previous stent implantation
  - Previous bypass graft(s)

    Difficult or impossible to image patients were not limited to these patient groups, but no other groups were identified during the review process. Following consultation with clinical experts, the definition of HHR (>70 bpm) specified in the protocol was broadened to avoid potential loss of relevant data, as identified studies frequently defined HHR as >65 bpm.
- Infants, children and adults diagnosed with complex congenital heart disease, including but not limited to:
  - Pulmonary atresia with major aortopulmonary collaterals (MAPCA)
  - Variants of anomalous pulmonary venous drainage (total anomalous pulmonary venous drainage [TAPVD], Scimitar syndrome, etc.)
  - Aortic arch abnormalities (double aortic arch, vascular ring, etc.)

- Lesions with both a vascular and airway component (pulmonary artery sling, tracheal stenosis, right aortic arch with aberrant subclavian artery, etc.)
- Previously treated lesions where stents or pacemakers make magnetic resonance imaging (MRI) an unsuitable imaging strategy

Setting

Relevant settings were secondary or tertiary care.

Interventions

Included interventions, described as 'NGCCT' (new generation cardiac computed tomography scanner) throughout, were the following CT scanners:

- Discovery CT750
- Brilliance iCT
- Somatom Definition Flash
- Aquilion One

No additional equivalent technologies were identified during the review process.

Comparators

The only relevant comparator for the assessment of difficult to image CAD patients was invasive coronary angiography (ICA).

Relevant comparators, for the assessment of complex congenital heart disease, were 64-slice CT, or conventional imaging (without CT).

Reference Standard

Studies reporting the diagnostic accuracy of NGCCT for the detection of significant CAD were required to use ICA as the reference standard. Diagnostic accuracy was not considered a relevant outcome for studies of congenital heart disease.

Outcomes

Studies reporting the following outcomes were considered relevant for both clinical applications (CAD and congenital heart disease):

- Impact of testing on treatment plan (e.g., surgical or medical management), where information on the appropriateness of the final treatment plan was also reported
- Impact of testing on clinical outcome (e.g., angina, myocardial infarction, cardiovascular mortality)

Studies reporting the following outcomes were considered relevant for difficult to image CAD patients only:

- Test accuracy
- Indeterminacy (test failure rate)

For included studies reporting any of the above outcome measures, the following outcomes were also recorded, if reported:

- Acceptability of tests to patients
- Adverse events associated with testing
- Radiation dose associated with imaging

Study Design

The following study designs were eligible for inclusion:

- Randomised or non-randomised controlled trials, where participants were assigned to the intervention or comparator tests, for treatment planning, and outcomes were compared at follow-up
- Randomised or non-randomised controlled trials where participants were assigned to conventional imaging only, or conventional imaging plus high definition or 64-slice CT (congenital heart disease only).

No randomised or non-randomised controlled trials were identified. Therefore, the following observational study types were considered eligible for inclusion:

- Cross-sectional test accuracy studies, where the intervention was compared with the reference standard (CAD only)
- Observational studies reporting change to treatment plan or clinical outcome subsequent to high definition CT (CAD and congenital heart disease), or 64-slice CT (congenital heart disease only).

Cross-sectional test accuracy studies were required to report the absolute numbers of true positive, false negative, false positive, and true negative test results, or sufficient information to allow their calculation.

The following study/publication types were excluded:

- Pre-clinical, animal and phantom studies
- Reviews, editorials, and opinion pieces
- Case reports
- Studies reporting only technical aspects of the test, or image quality
- Studies with <10 participants

Search Strategy

Search strategies were be based on target condition and intervention, as recommended in the Centre for Reviews and Dissemination (CRD) guidance for undertaking reviews in health care and the Cochrane Handbook for Diagnostic Test Accuracy Reviews.

The following databases were searched for relevant studies from 2000 to February/March 2011:

- MEDLINE (2000-2011/02/wk 2) (OvidSP)
- MEDLINE In-Process Citations and Daily Update (2000-2011/02/16) (OvidSP)
- EMBASE (2000-2011/wk 6) (OvidSP)
- Cochrane Database of Systematic Reviews (CDSR) (Cochrane Library Issue 1:2011) (Wiley)
- Cochrane Central Register of Controlled Trials (CENTRAL) (Cochrane Library Issue 1:2011) (Wiley)
- Database of Abstracts of Reviews of Effects (DARE) (2000-2011/03/09) (CRD website)
- National Health Service Economic Evaluation Database (NHS EED) (2000-2011/03/09) (CRD website)
- Health Technology Assessment Database (HTA) (2000-2011/03/09) (CRD website)
- Science Citation Index (SCI) (2000-2011/03/05) (Web of Science)

See Section 5.2 in the DAR for supplementary research sources and electronic searches for conference abstracts.

Searches were undertaken to identify studies of NGCCT in the diagnosis of CAD and assessment of congenital heart disease. Search strategies were developed specifically for each database and the keywords associated with CAD and congenital heart defects were adapted according to the configuration of each database. Searches took into account generic and other product names for the intervention. No restrictions on language or publication status were applied. Limits were applied to remove animal studies. Full search strategies are reported in Appendix 1 in the DAR (see the "Availability of Companion Documents" field).

Identified references were downloaded in Endnote X4 software for further assessment and handling. References in retrieved articles were checked for additional studies.

Inclusion Screening

Two reviewers independently screened the titles and abstracts of all reports identified by searches and any discrepancies were discussed and resolved by consensus. Full copies of all studies deemed potentially relevant, after discussion, were obtained and the same two reviewers independently assessed these for inclusion; any disagreements were resolved by consensus. Details of studies excluded at the full paper screening stage are presented in Appendix 5 in the DAR (see the "Availability of Companion Documents" field).

Studies listed in submissions from the manufacturers of NGCCT were first checked against the project reference database, in Endnote X4; any studies not already identified by the searches were screened for inclusion following the process described above. Studies referenced by manufacturers and excluded at the full paper screening stage are noted in Appendix 5 in the DAR (see the "Availability of Companion Documents" field). Appendix 5 also includes a list of studies, referenced by manufacturers, which were excluded at title and abstract screening.

Where there was uncertainty regarding possible overlap between study populations, authors were contacted for clarification.

Assessment of Cost-effectiveness

Search Strategy

Searches were undertaken to identify cost-effectiveness studies of NGCCT. As with the clinical effectiveness searching, search strategies were developed specifically for each database and searches took into account generic and other product names for the intervention. No restrictions on language or publication status were applied. Limits were applied to remove animal studies. Full search strategies are reported in Appendix 1 in the DAR (see the "Availability of Companion Documents" field).

The following databases were searched for relevant studies from 2000 to present:

- MEDLINE (2000-2011/03/wk 2) (OvidSP)
- MEDLINE In-Process Citations and Daily Update (2000-2011/03/17) (OvidSP)
- EMBASE (2000-2011/wk 11) (OvidSP)
- NHS EED (2000-2011/03/09) (CRD website)
- Health Economic Evaluation Database (2000-2011/03/09) (Wiley) http://onlinelibrary.wiley.com/book/10.1002/9780470510933
- Paediatric Economic Database Evaluation (PEDE) (2000-2011/03/05) (Internet) http://pede.ccb.sickkids.ca/pede/search.jsp

See Section 6.1 in the DAR for supplementary search resources.

Identified references were downloaded in Endnote X4 software for further assessment and handling. References in retrieved articles were checked for additional studies.

Number of Source Documents

Assessment of Clinical Effectiveness

The literature searches of bibliographic databases identified 3986 references. After initial screening of titles and abstracts, 119 were considered to be potentially relevant and ordered for full paper screening. A further 11 papers were ordered based on screening of submissions from industry and two studies cited in trials registry entries were also obtained. Of the total of 132 publications considered potentially relevant, five could not be obtained within the time scale of this assessment. Figure 1 in the Diagnostics Assessment Report (DAR) shows the flow of studies through the review process, and Appendix 5 in the DAR provides details, with reasons for exclusions, of all publications excluded at the full paper screening stage (see the "Availability of Companion Documents" field).

Twenty-three publications of 21 studies were included in the review. Hand searching of conference proceedings resulted in the inclusion of a further three studies, which were published in abstract form only. A total of 24 studies in 26 publications were, therefore, included in the review. No studies were identified, of patients with congenital heart disease, which met the inclusion criteria of the review.

Assessment of Cost-effectiveness

Five models were combined to estimate the cost-effectiveness.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an External Assessment Group to perform a systematic literature review on the technology considered in this diagnostics guidance and prepare a Diagnostics Assessment Report (DAR). The DAR for this guidance was prepared by Kleijnen Systematic Reviews Ltd. (see the "Availability of Companion Documents" field).

Assessment of Clinical Effectiveness

Data Extraction

Data were extracted on: study details (study design, participant recruitment, setting, funding, stated objective, and categories of participants relevant to this assessment for whom data were reported); study participants (total number of participants, number of participants in each relevant group, study inclusion criteria, study exclusion criteria, and participant characteristics relevant to cardiovascular risk for the relevant participant groups or the whole study population); assessed technology and reference standard (technical details of the test, any use of β-blockers prior to scanning, details of who interpreted tests and how, threshold used to define a positive test); study results. All studies included in the review were diagnostic accuracy studies and the results extracted were: unit of analysis (patient, artery, or arterial segment; numbers of true positive, false negative, false positive, and true negative test results; numbers of patients, arteries, or segments classified as non-diagnostic by new generation cardiac computed tomography (NGCCT) scanners; radiation exposure associated with imaging. All data were extracted by one reviewer, using a piloted, standard data extraction form and checked by a second; any disagreements were resolved by consensus. Full data extraction tables are provided in Appendix 4 in the DAR (see the "Availability of Companion Documents" field).

Quality Assessment

All studies included in the systematic review were test accuracy studies. The Quality Assessment of Diagnostic Accuracy studies (QUADAS) tool is recommended for assessing the methodological quality of test accuracy studies. However, a revised version of QUADAS (QUADAS-2) was published in 2011 (www.quadas.org). QUADAS-2 more closely resembles the approach and structure of the Cochrane risk of bias tool. QUADAS-2 separates bias from external validity (applicability) and does not include any items which only assess reporting quality. Guidance for the use of QUADAS-2 will emphasise the need to tailor the tool to specific projects and the need to avoid the use of summary quality scores.

Review-specific guidance was produced for the use of QUADAS-2 in this assessment and is reported in Appendix 2 in the DAR (see the "Availability of Companion Documents" field).

The results of the quality assessment are summarised and presented in tables and graphs in Section 5.6 in the DAR and are presented in full, by study, in Appendix 3 in the DAR (see the "Availability of Companion Documents" field). No diagnostic accuracy data set included in this assessment was of sufficient size to allow statistical exploration of between study heterogeneity based on aspects of risk of bias. The findings of the quality assessment were also used to inform recommendations for future research.

Methods of Analysis/Synthesis

All studies included in the systematic review were test accuracy studies in difficult to image coronary artery disease (CAD) patients. Results were summarised by patient group (e.g., obese, high heart rate, high coronary calcium score, etc.) and further stratified by unit of analysis (patient, artery, or arterial segment). For all included studies, the absolute numbers of true positive, false negative, false positive and true negative test results, as well as sensitivity and specificity values, with 95% confidence intervals (CIs) were presented in results tables, for each patient group reported. Data on the numbers of non-diagnostic tests and radiation exposure were also included in the results tables and described in text summaries.

Where groups of similar studies (same patient group and unit of analysis) included four or more data sets, summary receiver operating characteristic (SROC) curves and summary estimates of sensitivity and specificity, with 95% CIs were calculated using the bivariate modelling approach; four data sets are the minimum requirement to fit models of this type. Analyses were conducted in STATA 10, using the 'metandi' function. In two cases, a bivariate model could not be fitted because the number of studies was small (four), 2 x 2 data contained one or more zero values, and between study heterogeneity was low. In these cases pooled estimates of sensitivity and specificity, with 95% CIs, were calculated using a random effects model; these analyses were conducted using MetaDiSc 1.4, and forest plots were constructed, showing the sensitivity and specificity estimates from each study together with pooled estimates. No distinction was made between patients with known or suspected CAD as per patient data sets were generally small, with low to moderate between study heterogeneity. In addition, 'known' and 'suspected' CAD were often poorly defined by the included studies.

Between study heterogeneity was assessed using the chi-squared test and inconsistency was quantified using the I^2 statistic. There were no data sets of sufficient size (minimum ten) to allow statistical exploration of sources of heterogeneity by including additional co-variables in the SROC model.

Where meta-analysis was considered unsuitable for the data identified (e.g., due to the heterogeneity and/or small numbers of studies), studies were summarised using a narrative synthesis. Text and tables were stratified by patient group.

No data were identified on the effects of NGCCT on treatment planning and/or clinical outcome, adverse events associated with testing, or acceptability of tests to patients.

Assessment of Cost-effectiveness

Model Structure and Methodology

The cost-effectiveness of NGCCT for difficult to image patient groups is estimated for two CAD populations: the suspected CAD population and the known CAD population. Patients suspected of CAD are patients who have chest pain or other symptoms suggestive of CAD. Patients with known CAD are patients who have previously been diagnosed with CAD and whose symptoms are no longer controlled by drug treatment and/or being considered for revascularisation. The use of NGCCT has different purposes in the two CAD populations: for the suspected CAD population the purpose is to diagnose patients with CAD and for the known CAD population the purpose is to decide if a revascularisation is necessary.

Five models were combined to estimate the cost-effectiveness of the NGCCT:

- A decision tree that models the diagnostic pathway (Diagnostic model)
- A life–death Markov model for "healthy" patients without CAD (Healthy population Markov model)
- A simple stroke model to estimate the impact of test and treatment related stroke (stroke model)
- A model for the prognosis of patients with CAD
- A model constructed by the Centre for Health Economics, University of York to model the impact of imaging due to radiation on cancer morbidity and mortality, hereafter referred to as the York Radiation Model (YRM)

The comparator used for the evaluation of suspected or known CAD in difficult or impossible to image patients was invasive coronary angiography (ICA). Three strategies were evaluated in this assessment. The first strategy (ICA-only) is a strategy where patients with suspected or known CAD only undergo an ICA. While ICA is the reference standard test and is assumed to be 100% sensitive and specific, it is associated with a risk of serious complications, including death, non-fatal myocardial infarction and stroke. NGCCT does not have a sensitivity and specificity of 100% and thus is less accurate than the ICA. The second strategy (NGCCT-ICA) evaluates the combination of cardiac CT using the new generation technologies and ICA. Cardiac CT is first performed in all patients and patients with a positive CT scan then undergo an ICA. This additional test will reveal any patients with a false positive CT test result, but it also provides other information that a CT currently does not. The third strategy (NGCCT only) uses only NGCCT to diagnose patients.

The five models used in the analyses are described, in detail, in Section 6 of the DAR. The stochastic analyses are based on cohort simulations. To investigate decision uncertainty, second-order uncertainty micro-simulations were run.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Developing Recommendations

After reviewing the evidence the Diagnostic Advisory Committee (DAC) agrees draft recommendations on the use of the technology in the National Health Service (NHS) in England. When formulating these recommendations, the Committee has discretion to consider those factors it believes are most appropriate to the evaluation. In doing so, the Committee has regard to any relevant provisions of the National Institute for Health and Care Excellence's (NICE's) Directions, set out by the Secretary of State for Health, and legislation on human rights, discrimination and equality. In undertaking evaluations of healthcare technologies, NICE takes into account the broad balance of clinical benefits and costs, the degree of clinical need of patients under consideration, any guidance issued to the NHS by the Secretary of State that is specifically drawn to the attention of NICE by the Secretary of State, and any guidance issued by the Secretary of State, and the potential for long-term benefits to the

NHS of innovation.

The Committee takes into account advice from NICE on the approach it should take to making scientific and social value judgements. Advice on social value judgements is informed in part by the work of NICE's Citizens Council.

The Committee takes into account how its judgements have a bearing on distributive justice or legal requirements in relation to human rights, discrimination and equality. Such characteristics include, but are not confined to: race, gender, disability, religion or belief, sexual orientation, gender reassignment and pregnancy or maternity.

The Committee considers the application of other Board-approved NICE methods policies, such as the supplementary guidance on discounting and the end-of-life criteria, if they are relevant to the evaluation.

Because the Programme often evaluates new technologies that have a thin evidence base, in formulating its recommendations the Committee balances the quality and quantity of evidence with the expected value of the technology to the NHS and the public.

The credibility of the guidance produced by NICE depends on the transparency of the DAC's decision-making process. It is crucial that the DAC's decisions are explained clearly, and that the contributions of registered stakeholders and the views of members of the public are considered. The reasoning behind the Committee's recommendations is explained, with reference to the factors that have been taken into account.

The language and style used in the documents produced by the Committee are governed by the following principles:

- Clarity is essential in explaining how the DAC has come to its conclusions.
- The text of the documents does not need to reiterate all the factual information that can be found in the information published alongside the guidance. This needs careful judgement so that enough information and justification is given in the recommendations to enable the reader to understand what evidence the DAC considered and, if appropriate, who provided that evidence.

The Committee may take into account factors that may provide benefits to the NHS or the population, such as patient convenience. It may also consider costs and other positive or negative impacts on the NHS that may not be captured in the reference-case cost analysis, such as improved processes.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Models were used to estimate the costs of the diagnostic tests and treatments people received for their initial conditions and any subsequent related conditions that developed. Although there is some variation in the costs of the new generation cardiac computed tomography (CT) scanners, the models assumed that each scanner cost £1 million.

The comparator, invasive coronary angiography, was presumed to be perfectly accurate (a gold standard) and, despite a known increase in complication rate compared with CT, generated more quality-adjusted life-year (QALY) gains than CT. It was also more expensive than imaging with a new generation cardiac CT scanner. The incremental cost-effectiveness ratio (ICER) of invasive angiography when compared with new generation cardiac CT is significantly greater than the National Institute for Health and Care Excellence (NICE) cost-effectiveness threshold.

In people with suspected coronary artery disease in whom imaging is difficult, the health economic analysis showed that, given a threshold of £20,000 per QALY gained, using new generation cardiac CT scanners instead of invasive coronary angiography is cost-effective. The 'new generation CT scanner only' strategy was the most cost-effective strategy. The 'new generation CT scan plus invasive coronary angiography for those with positive CT scans' strategy delivered very small additional QALYS per patient (0.002) at a cost of £142. The incremental ICER was £71,000 per QALY gained compared to the 'new generation CT scanner only' strategy. Similarly, relative to the 'new generation CT scanner only' strategy, 'invasive coronary angiography alone' also delivered a very small number of additional QALYS per patient (0.009) at a cost of £726 (ICER of £80,667 per QALY gained).

In people with known coronary artery disease who are difficult to image, the most cost-effective strategy was 'new generation cardiac CT scan plus invasive coronary angiography' for those with positive CT scans. This strategy dominated (more effective and less costly) the 'invasive coronary angiography only' strategy, generating more QALYs per patient (0.022) at reduced cost. The 'new generation cardiac CT scan plus invasive coronary angiography' strategy was the most preferred strategy for this cohort. Although it generated a very small reduction in QALYs per

patient (0.001), it yielded a relatively large reduction in cost (£443) (ICER £726,230 per QALY) relative to the 'new generation cardiac CT scan only.

See Sections 5 and 6 in the original guideline document for additional information on cost-effectiveness.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

The National Institute for Health and Care Excellence (NICE) sends the Diagnostics Assessment Report (DAR), with any confidential material removed, to registered stakeholders for comment. Stakeholders have 10 working days to return comments. Models supporting the DAR are made available to registered stakeholders on request during this period.

NICE presents anonymised registered stakeholder comments on the DAR, along with any responses from NICE or the External Assessment Group (EAG), to the Committee and later publishes these comments on its website.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Diagnostics Advisory Committee considered clinical and cost-effectiveness evidence from a systematic review of computed tomography (CT) scanners for cardiac imaging performed by an External Assessment Group.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of new generation cardiac computed tomography (CT) scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD, and Somatom Definition Flash) for cardiac imaging in people with suspected or known coronary artery disease in whom imaging is difficult with earlier generation CT scanners

Potential Harms

False-positive and false-negative results

Qualifying Statements

Qualifying Statements

- This guidance represents the view of the National Institute for Health and Care Excellence (NICE), which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded

that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

The National Institute for Health and Care Excellence (NICE) has developed a costing statement (see also the "Availability of Companion Documents" field) explaining the resource impact of this guidance.

Implementation Tools

Mobile Device Resources

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). New generation cardiac CT scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash) for cardiac imaging in people with suspected or known coronary artery disease in whom imaging is difficult with earlier generation CT scanners. London (UK): National Institute for Health and Care Excellence (NICE); 2012 Jan. 32 p. (Diagnostics guidance; no. 3).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Jan

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Diagnostics Advisory Committee

Composition of Group That Authored the Guideline

Standing Committee Members: Dr Trevor Cole, Consultant Clinical Geneticist, Birmingham Women's Hospital Foundation Trust; Dr Paul O Collinson, Chemical Pathologist, St George's Hospital Professor; Ian Cree, Director of Efficacy and Mechanisms Programme, NIHR Evaluation, Trials and Studies Coordinating Centre; Dr Erika Denton, National Clinical Director for Imaging, Department of Health; Dr Simon Fleming, Consultant in Clinical Biochemistry and Metabolic Medicine, Royal Cornwall Hospital; Professor Elizabeth (Lisa) Hall, Professor of Analytical Biotechnology, Institute of Biotechnology, Department of Chemical Engineering and Biotechnology, University of Cambridge; Professor Chris Hyde, Professor of Public Health and Clinical Epidemiology, Peninsula College of Medicine and Dentistry; Professor Noor Kalsheker, Professor of Clinical Chemistry, Molecular Medical Sciences, University of Nottingham; Dr Mark Kroese, Consultant in Public Health Medicine, Peterborough Primary Care Trust and UK Genetic Testing Network; Professor Dietrich Mack, Professor of Medical Microbiology and Infectious Disease, School of Medicine, Swansea University; Professor Adrian Newland (*Chair*), Consultant Haematologist, Barts and the London NHS Trust; Dr Richard Nicholas, Consultant Neurologist, Heatherwood and Wexham Park Hospital, Imperial Healthcare Trust; Ms Margaret Ogden, Lay member; Dr Diego Ossa, Global Head, Health Economic and Outcomes Research, Novartis Molecular Diagnostics; Mr Stuart Saw, Director of Finance and Procurement, Tower Hamlets PCT; Professor Mark Sculpher, Professor of Health Economics, Centre for Health Economics, University of York; Dr Steve Thomas, Senior Lecturer and Consultant Radiologist, University of Sheffield; Mr Paul Weinberger, Director, Diasolve Ltd; Mr Christopher Wiltsher, Lay member

Specialist Committee Members: Ms Anne Keatley-Clarke, Lay member; Mrs Susan Ruth Clarke, Consultant Radiographer, Mid Yorkshire NHS Trust; Dr Owen Miller, Consultant in Paediatric and Fetal Cardiology, Evelina Children's Hospital; Dr Simon Padley, Consultant Radiologist, Chelsea and Westminster Hospital and Royal Brompton Hospital; Dr Francesca Puglese, Consultant Radiologist, Barts and the London NHS Trust; Professor Carl Roobottom, Professor of Radiology, Peninsula College of Medicine and Dentistry; Dr Ramesh de Silva, Consultant Cardiologist, Bedford Hospital NHS Trust; Mr John Walsh, Lay member

Financial Disclosures/Conflicts of Interest

Committee members are required to submit a declaration of interests on appointment, in every year of their tenure, and at each Committee meeting, in line with the National Institute for Health and Care Excellence's (NICE's) code of practice for declaring and dealing with conflicts of interest.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site. Also available for download as a Kindle or EPUB ebook from the NICE Web site.

Availability of Companion Documents

The following are available:

- Westwood M, Al MJ, Burgers LT, Redekop WK, Lhachimi SK, Armstrong N, Raatz H, Misso K, Severens JL, Kleijnen J. Computed tomography (CT) scanners for cardiac imaging – Somatom Definition Flash, Aquilion One, Brilliance iCT and Discovery CT750 HD. Diagnostics assessment report. York (UK): Kleijnen Systematic Reviews Ltd.; 2011. 336 p. Electronic copies: Available in from the National Institute for Health and Care Excellence (NICE) Web site.
- Westwood M, Al MJ, Burgers LT, Redekop WK, Lhachimi SK, Armstrong N, Raatz H, Misso K, Severens JL, Kleijnen J. Computed tomography (CT) scanners for cardiac imaging – Somatom Definition Flash, Aquilion One, Brilliance iCT and Discovery CT750 HD. DAR appendices. York (UK): Kleijnen Systematic Reviews Ltd.; 2011. 126 p. Electronic copies: Available in from the NICE Web site.
- New generation cardiac CT scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash) for cardiac imaging in people with suspected or known coronary artery disease in whom imaging is difficult with earlier generation CT scanners. Costing statement. London (UK): National Institute for Health and Care Excellence (NICE); 2012 Jan. 6 p. (Diagnostics guidance; no. 3). Electronic copies: Available from the NICE Web site.
- Diagnostics Assessment Programme manual. London (UK): National Institute for Health and Care Excellence; 2011 Dec. 130 p. Electronic copies: Available from the NICE Web site.

Patient Resources

The following is available:

- New generation cardiac CT scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash) for cardiac imaging in people with suspected or known coronary artery disease in whom imaging is difficult with earlier generation CT scanners. Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2012 Jan. (Diagnostics guidance; no. 3). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site.

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